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Visual performance of early presbyopes fitted with contact lenses

Submission date 25/08/2026	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 27/08/2026	**Overall study status** Ongoing	
Last Edited 26/08/2026	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims
The aim of the current study is to compare the vision performance of MyDay sphere & MyDay Energys in a group of 40 to 50 year old participants.

Who can participate?
Adult patients aged between 40 to 50 years with early presbyopia.

What does the study involve?
The participants will attend the clinic for two study visits :
During the first visit the participant will be fitted with the control contact lenses and their study contact lens prescription will be determined.
During the second visit the participant will be fitted with both the test and control study contact selected in random order. The visual performance and quality of vision will be assessed by the investigators.

What are the possible benefits and risks of participating?
Participants have the opportunity to try contact lenses.
Any contact lens wear comes at the risk of corneal infection, but the incidence rate is very low.

Where is the study run from?
Ocular Technology Group International, London.

When is the study starting and how long is it expected to run for?
This study will start in August 2026 and run for 12 months.

Who is funding the study?
CooperVision International Limited.

Who is the main contact?
Deborah Moore, dmoore@otg.co.uk

Contact information

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Principal investigator, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
373390

Protocol number
CV26-29

Study information

Scientific Title
Visual performance of early presbyopes fitted with contact lenses

Study objectives
The primary objective of the study will be to compare the visual performance, in conditions representing everyday challenging visual environments, of MyDay® Energys® contact lenses with that of MyDay® sphere in a population of 40 and over years old with emergent presbyopia.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 24/07/2026, West of Scotland REC 5 (Admin Building, Level 2 Gartnavel Royal Hospital 1055 Great Western Road, Glasgow, G12 0XH, United Kingdom; Not available; ggc.wosrec5@nhs.scot), ref: 26/WS/0107

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Crossover

Purpose
The primary purpose of the study will be to compare the visual performance, in conditions representing everyday challenging visual environments, of MyDay® Energys® contact lenses with that of MyDay® sphere in a population of 40 to 50 years old.

Study type(s)

Health condition(s) or problem(s) studied
Early presbyopia

Interventions
Up to 30 potential participants will attend the research clinic for the first visit (screening / enrolment / test familiarisation visit) to initially obtain their informed consent and screen them for their suitability to take part in the investigation. They will be asked to attend the clinic wearing their spectacles, the potential participants will not have worn their contact lenses prior to the visit the day of the visit. After informed consent has been given, the investigator will review the participant's medical history, ocular history (including concomitant treatments), demographics and contact lens wear history. A series of routine optometric assessments and tests will be conducted to determine the participant's prescription and evaluate the participant's ocular health. Once it has been verified that the participants meet the inclusion/exclusion criteria they will be considered as enrolled, and they will be fitted with the control contact lenses and familiarize with the study tests. At the conclusion of the visit the participants will be scheduled to attend the study test visit.

The participants will return for the second visit (test visit) wearing their spectacles and will not have worn their contact lenses prior to the visit the day of the visit. Their concomitant medications will once again be reviewed. The test or control contact lens (randomised) will be inserted and worn for 15 minutes. 15 minutes later a set of visual performance tests and vision quality questionnaires will be carried out. The order 1 study contact lens will be removed, and

the second contact lens will be inserted, and the same routine will be repeated. At the end of the study contact lens order 2 will be removed and safety ocular integrity evaluation will be carried before discharge from the study.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
MyDay® sphere & MyDay® Energys®

Primary outcome(s)
1. Measurement of visual Performances of MyDay® sphere & MyDay® Energys® measured using under 50cd/m2 luminance with low contrast (10%) timed logMAR vision acuity at visit 2

Key secondary outcome(s)

Completion date
30/11/2026

Eligibility

Key inclusion criteria
1. Age 40 to 50 years old
2. Have read and understood the participant Information Sheet
3. Have read, signed and dated the Informe Consent
4. Best corrected visual acuity of at least 20/25 in each eye
5. Have normal eyes with the exception of the need for visual correction
6. Current single vision contact lenses wearer.
7. Spectacle refraction:
7.1. Distance Sphere: -6.00D to + 2.00D
7.2. Astigmatism: 0.00D to -0.75D
7.3. Near Addition: +0.50D & +0.75D
8. Be willing and able to adhere to the instructions set in the clinical protocol and maintain the appointment schedule

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
40 Years

Upper age limit
50 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Acute and subacute inflammation or infection of the anterior chamber of the eye
2. Any eye disease, injury or abnormality that affects the cornea, conjunctiva or eyelids that would contraindicate contact lens wear
3. Corneal hypoesthesia (reduced corneal sensitivity), if not aphakic
4. Severe insufficiency of lacrimal secretion (dry eyes)
5. Any systemic disease that may affect the eye or may be exaggerated by wearing contact lenses (e.g. acne and eczema)
6. Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
7. Any active corneal infection (bacterial, fungal, protozoal or viral)
8. Newly prescribed (within the past 30 days) use of some systemic medications (such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, stimulants, anti-depressants, anti-psychotics, oral contraceptives) or new prescription eyedrops which is not rewetting/lubricating eyedrops for which contact lens wear could be contraindicated as determined by the investigator
9. Monocular participants (only one eye with functional vision) or participants fit with only one contact lens
10. Monovision wearer
11. Subjects with slit lamp findings greater than grade 1 (e.g. Oedema, infiltrates, corneal neovascularization, corneal staining, tarsal abnormalities, conjunctival, anterior segment inflammation) as recorded during the clinical visit, any previous history or signs of a contact lens related corneal inflammatory event (past corneal ulcers), or any other ocular abnormality that may contraindicate contact lens wear at the enrolment visit
12. Pregnancy, lactating, History herpetic keratitis
13. History of corneal refractive surgery
14. Enrolment of the family members of the investigator, family members of the investigator’s staff, or individuals living in the households of these individuals

Date of first enrolment
30/08/2026

Date of final enrolment
10/11/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Ocular Technology Group International
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Sponsor information

Organisation
CooperVision International Limited

Funder(s)

Funder type

Funder Name
CooperVision International Limited

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available